REMARKS

Reconsideration of this application is respectfully requested in view of the following remarks. No claims have been canceled, amended, or added.

In the Office Action mailed March 9, 2007, claims 12 and 17-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,613,064 to Rutynowski et al. ("Rutynowski") in view of U.S. Patent No. 5,871,494 to Simons et al. ("Simons"). Claims 3-4, 8-11, and 13-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rutynowski in view of Simons, and further in view of U.S. Patent No. 6,558,402 to Chelak et al. ("Chelak"). Applicant respectfully traverses these rejections. The following remarks are organized under subheadings corresponding to the rejections.

35 U.S.C. §103(a): Claims 12 and 17-19

In rejecting claims 12 and 17-19, the Examiner correctly noted that Rutynowski fails to disclose a force-adjusting member, which is recited as an adjustable push element in independent claim 12. For that limitation, the Examiner cited the cartridge holder 502 and force adjuster 528 of Simons, explaining that those elements adjust "a distance within which the ***spring 532*** is compressed." (Office Action, page 3, line 20 to page 4, line 3, emphasis added.) That spring 532 of Simons, however, is not a drive spring and in no way affects the puncturing force of the lancet 216. Instead, force adjuster 528 and spring 532 merely adjust the force required to push the contact-activated Simons device against the skin to activate the device. (Column 11, lines 12-13 and column 12, lines 30-37 and 60-64.) Indeed, the "force adjusting" of Simons relates to that press against the skin and the preload skin tension, which is wholly different from the

present invention's adjustment of the initial biasing of the drive spring (*i.e.*, the distance of compression of the spring) to set the force with which the puncturing tip pierces the skin. Importantly, in Simons, the distance over which its drive spring 552 is compressed never changes.

Simons discloses a multiple usage puncturing device intended for use with renewable lancet cartridges. The Simons device permits adjustment of both the puncture depth of the lancet and also the preload force applied to the skin before lancing. (Column 11, lines 12-13.) The preload force is adjustable by changing the degree of compression of the adjuster spring 532 of force adjuster 528. In this type of contact puncturing device, adjusting this preload force affects the skin tension at the place of puncture, which is a clear concern discussed in the Background section of Simons (column 3, lines 31-38), the Detailed Description (*see, e.g.*, column 12, lines 55-56.), and the Abstract (last sentence). In fact, the sole concern of Simons is regulating the puncture depth, which is affected by both the distance by which the lancet 216 extends from the test cartridge 210 (adjustable by depth adjuster 560) and also the preload force as it affects the tautness of the skin (adjustable by force adjuster 528).

In contrast, in the present invention, push element 2 can be adjusted to vary the *degree of compression of drive spring 10* at the point at which the wings 12 are broken, and thereby adjust the force with which the puncturing tip 8 is driven into the skin. (*See, e.g.*, specification at page 8, lines 14-17 and page 8, line 26 to page 9, line 2.) Presently pending independent claim 12 recites this feature, for example, in the final two paragraphs ("the adjustable push element configured to change the distance…the drive spring being compressed until…"). The present

invention therefore can change the distance within which the drive spring 10 is compressed when it is released (*i.e.*, when the wings 12 break), to change the force with which puncturing tip 8 is propelled forward. In contrast, Simons compresses the drive spring 552 the same distance every time, thereby propelling the tip 216 with the same force every time.

For at least the above reasons, Applicants respectfully submit that independent claim 12 is patentable over Rutynowski and Simons. In addition, Applicants respectfully submit that dependent claims 12-19 are also patentable due at least to their dependence on an allowable base claim.

35 U.S.C. §103(a): Claims 3-4, 8-11, and 13-16

As with independent claim 12, the Examiner's rejection of independent claims 3 and 4 relied on the combination of Rutynowski and Simons. And, similar to claim 12, claims 3 and 4 recite a puncturing force adjusting member that presses the piston in operation, thereby adjusting the degree of compression of the drive spring positioned between the face of the push element and the piston. Thus, at least for the reasons explained above with respect to claim 12, Applicants respectfully submit that claims 3 and 4 are also patentable over Rutynowski and Simons, and that dependent claims 8-11 and 13-16 are also patentable due at least to their dependence on an allowable base claim. In addition, Chelak fails to cure the deficiencies in Rutynowski and Simons.

Furthermore, Applicants respectfully traverse the Examiner's assertion that the half-ring or stair shaped features recited in claims 3 and 4, respectively, would have been obvious design choices. In particular, Applicant disagrees that such modifications would amount to design

choices that serve the same purpose of varying preload, because, as explained in detail above, the skin tension "preload" of Simons is wholly different from the adjustable puncture force of the present invention. Thus, the half-ring or stair shaped features would not be a simple design choice of changing a shape.

The puncturing force adjusting member of claims 3 and 4 have a completely different purpose (*i.e.*, needle impact force adjustment rather than needle depth adjustment) and carry out this purpose by interacting with entirely different parts and in a different manner than the depth adjusting member 106 of Chelak (*see, e.g.*, column 7, lines 65-66). Further, the claimed force adjusting member in the present invention modifies the operation of the device by providing the ability to adjust the force of impact of the needle depending on the patient's skin type or other concerns, and may therefore have the advantage of reducing painful effects of the puncturing device. That is, for patients with thin, delicate skin, the force of impact may be reduced so that the patient feels less pain at the *same depth* of penetration. For patients with thicker skin, the force of impact of the needle may be increased so as to ensure an adequate depth of penetration. These adjustments cannot be made in the device of Chelak.

Similarly, Applicants respectfully traverse the Examiner's assertion that the puncturing force adjusting member recited in claims 3 and 4 is an obvious shifting of location of a part disclosed in the combination of Rutynowski, Simons, and Chelak. In the first instance, as explained above, no equivalent element is taught or suggested by the applied combination. Moreover, even if the element were taught (which it is not), a puncturing device that only limits depth of penetration without regard to the force of impact runs the risk of causing unnecessary

pain in patients with thin skin and insufficient blood-sampling in patients with thick skin. The puncturing tip force adjusting capability of the present invention therefore provides an additional layer of adaptation in meeting specific patient needs and therefore represents a significant modification over the prior art. Since a modification exists and this case is not a mere rearrangement of inconsequential parts as in *Japikse*, Applicants respectfully submit that this obviousness rejection is improper and, accordingly, Applicants respectfully request its withdrawal.

As evidence of this non-obviousness, Applicants are submitting the attached Graphs I-IV and Table, which compare devices having different configurations for regulating puncture depth and/or puncture force. Graphs I-IV illustrate, for different devices, the puncturing tip forces generated by the drive spring and the retraction forces generated by the return spring. The table compares functions and effects obtained in the puncturing devices provided with different regulation systems. Graphs I-IV also each depict a common area of covering energies for both drive and return springs, whereas energy transferred to the skin is the difference between the drive spring energy and the return spring energy.

Graph I illustrates the dependency of force and energy of the drive and return springs in a puncturing device without puncturing depth and force regulations. In this device, the puncturing energy accumulated in the drive spring and transferred by puncturing needle into the skin is constant and the return energy accumulated in the return spring is constant due to the lack of any regulation of the distance of the drive and return spring lead. This device does not have the

ability to regulate the amount of blood drawn nor the amount of energy transferred into the patient's body during puncturing.

Graph II illustrates the dependency of force and energy of the drive and return springs in a puncturing device with the puncture depth regulation (*e.g.*, as in Rutynowski). The intended puncturing depth regulation influences the change of the energy accumulated in the return spring, but the puncturing energy is constant. This device has the ability to regulate the amount of blood drawn, but cannot regulate the amount of energy transferred into the patient's body during puncturing.

Graph III illustrates the dependency of force and energy of the drive and return springs in a puncturing device having the puncturing force regulation features of the present invention, but no depth adjustment. This device does not have the ability to regulate the amount of blood drawn, but can regulate the energy transferred into the patient's body during puncturing.

Graph IV illustrates the dependency of force and energy of the drive and return springs in a puncturing device with both puncturing depth regulation (*e.g.*, as in Rutynowski) and also puncturing force regulation as in the present invention. This device has the ability to simultaneously regulate the amount of blood drawn and the amount of energy transferred into the patient's body during puncturing.

From these graphs and table, it is apparent that the puncturing force regulation feature of the present invention is a significant non-obvious distinction over the prior art, which can accommodate a wide range of different patients. In addition, the graphs show that the different structure results in different operations and functions.

Applicants therefore respectfully submit that independent claims 3 and 4 are patentable over the combination of Rutynowski, Simons, and Chelak. In addition, Applicants respectfully submit that dependent claims 8-11 and 13-16 are also patentable due at least to their dependence on an allowable base claim.

In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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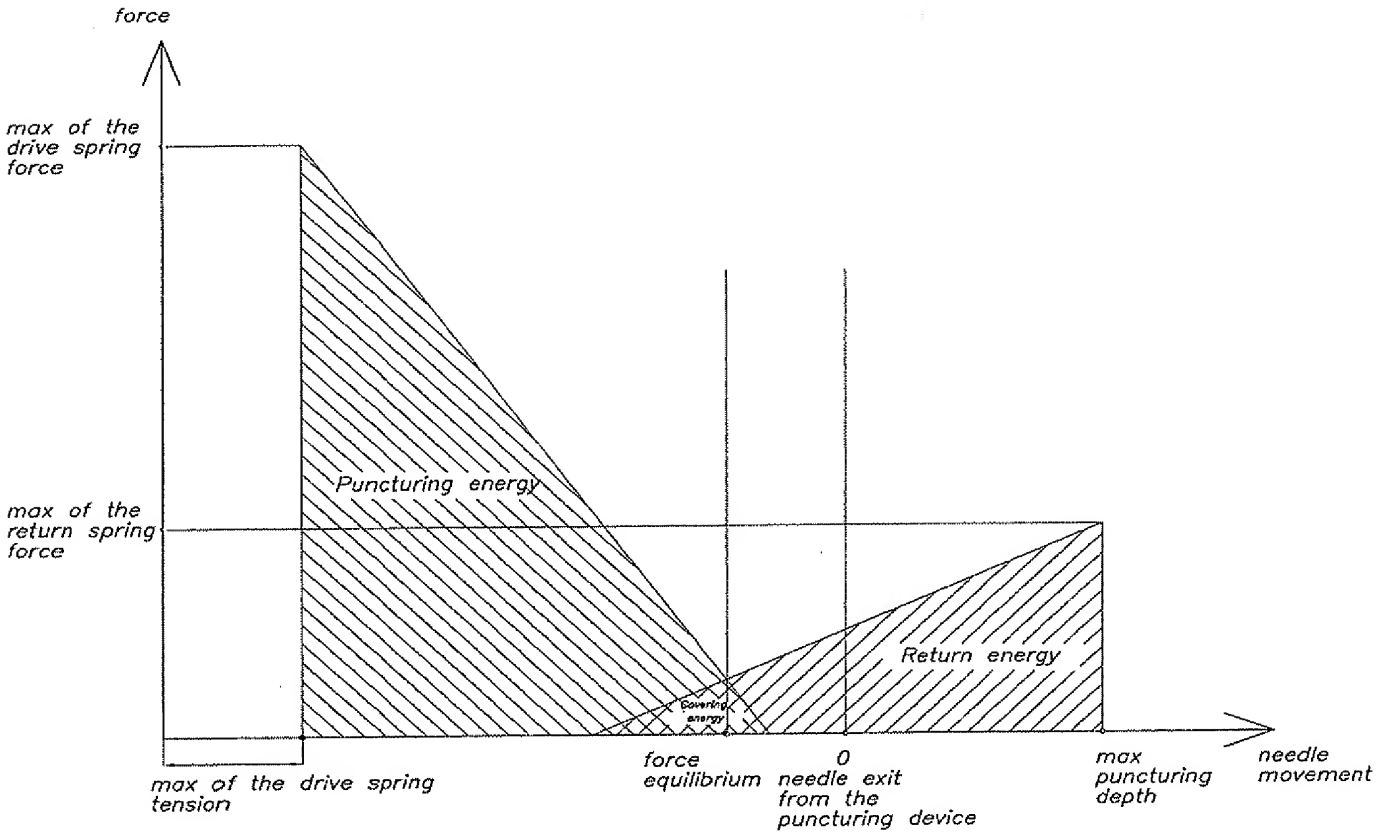
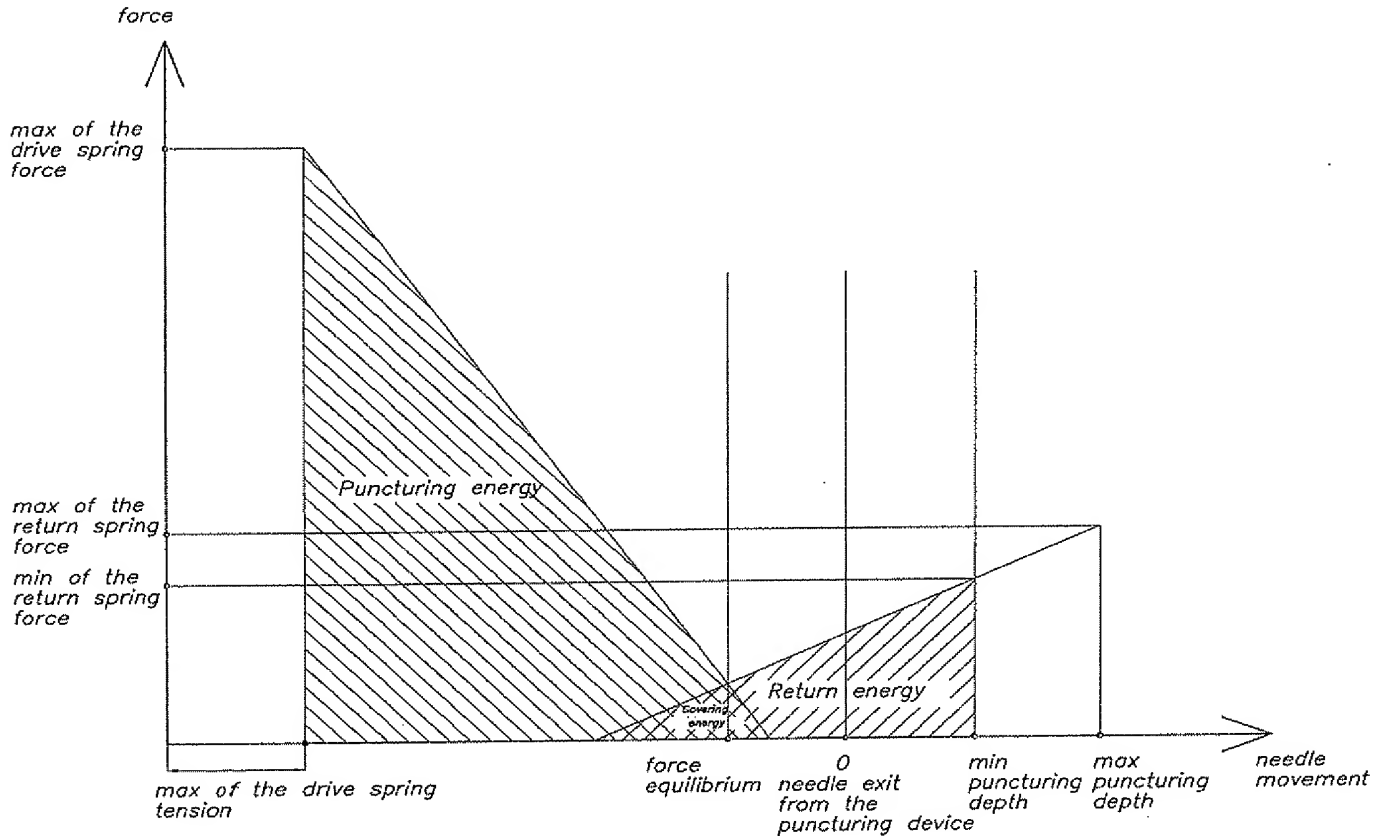
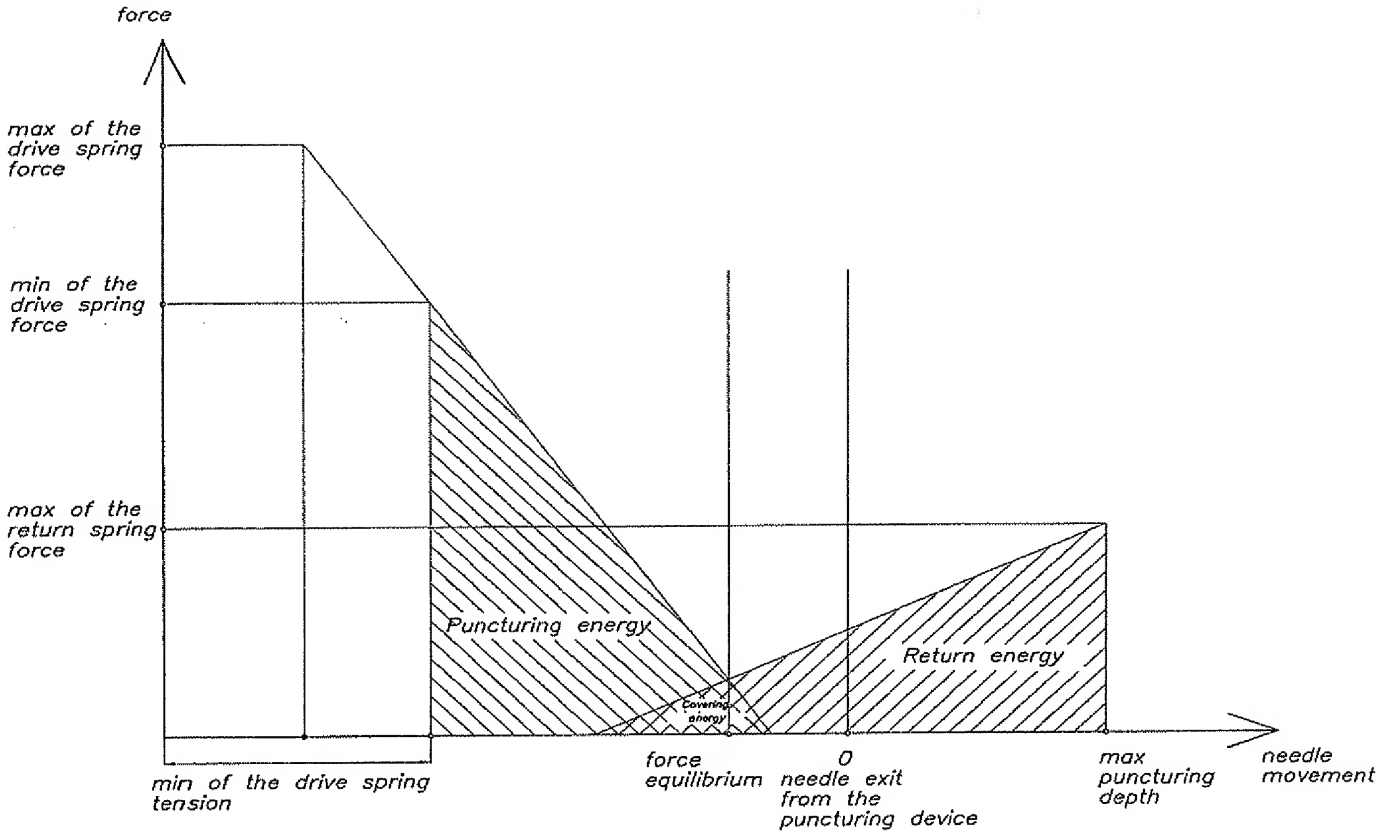


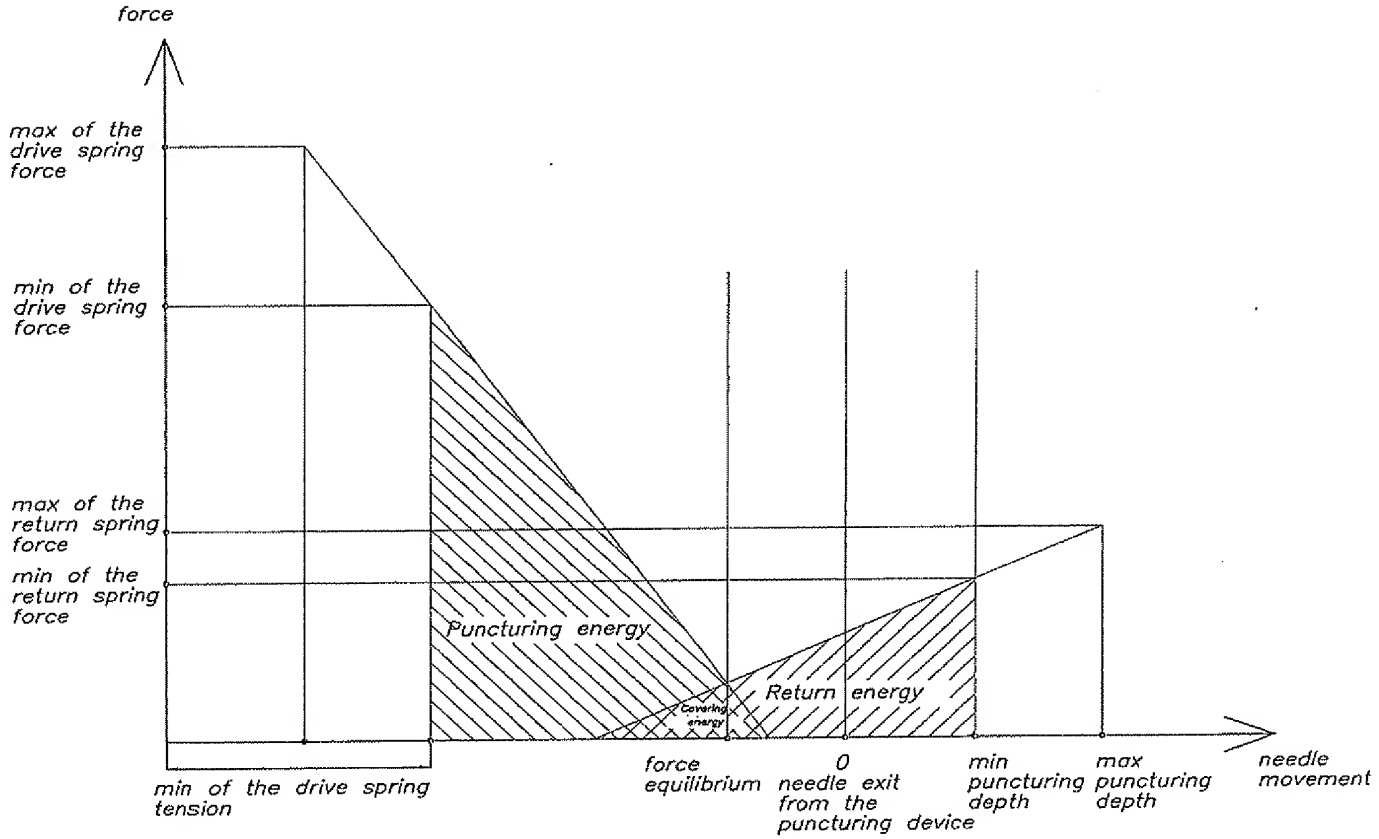
Graph I — Forces and energy in the puncturing device with no regulation



Graph II — Forces and energy in the puncturing device with puncture depth regulation



Graph III – Forces and energy in the puncturing device with puncture energy regulation



Graph IV – Forces and energy in the puncturing device with both regulations of puncture and depth regulation

force/energy

TABLE

	Accommodation to:	
	Required blood amount (puncture depth regulation in the sleeve bottom)	Skin type (puncture energy regulation in the push button)
I	–	–
II	+	–
III	–	+
IV	+	+

Possible regulations in the systems